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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,583	07/11/2002	Joyce S. Plested	11560-003US1	2536
27130	7590	11/02/2005	EXAMINER	
EITAN, PEARL, LATZER & COHEN ZEDEK LLP 10 ROCKEFELLER PLAZA, SUITE 1001 NEW YORK, NY 10020			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/089,583	PLESTED ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 48-53 and 55-60 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48-53 and 55-60 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **RESPONSE TO APPLICANTS' AMENDMENT**

### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 08/16/05 in response to the non-final Office Action mailed 05/16/05.

### **Status of Claims**

- 2) Claims 19, 29-41, 54 and 61 have been canceled via the amendment filed 05/16/05.  
Claims 48, 50, 53, 55 and 57-60 have been amended via the amendment filed 05/16/05.  
Claims 48-53 and 55-60 are pending and are under examination.

### **Prior Citation of Title 35 Sections**

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

### **Prior Citation of References**

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

### **Rejection(s) Moot**

- 5) The rejection of claims 54 and 61 made in paragraph 15 of the Office Action mailed 05/16/05 under 35 U.S.C § 112, first paragraph, as being as containing new subject matter, is moot in light of Applicants' cancellation of the claims.
- 6) The rejection of claims 54 and 61 made in paragraph 17 of the Office Action mailed 05/16/05 under 35 U.S.C § 102(b) as being anticipated by Arumugham *et al.* (EP 0941738, already of record) as evidenced by Plested *et al.* (*J. Immunol. Methods* 237: 73-84, 2000 – Applicants' IDS) (Plested *et al.*, 2000), is moot in light of Applicants' cancellation of the claims.

### **Rejection(s) Withdrawn**

- 7) The rejection of claims 48-53 and 55-60 made in paragraph 15 of the Office Action mailed 05/16/05 under 35 U.S.C § 112, first paragraph, as being as containing new subject matter, is withdrawn in light of Applicants' amendments to the claims and/or the base claims. A modified rejection is set forth below.

- 8) The rejection of claim 53 made in paragraph 16(a) of the Office Action mailed 05/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.
- 9) The rejection of claims 50-53 and 60 made in paragraph 16(b) of the Office Action mailed 05/16/05 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.
- 10) The rejection of claims 48-53 and 55-60 made in paragraph 17 of the Office Action mailed 05/16/05 under 35 U.S.C § 102(b) as being anticipated by Arumugham *et al.* (EP 0941738, already of record) as evidenced by Plested *et al.* (*J. Immunol. Methods* 237: 73-84, 2000 – Applicants' IDS) (Plested *et al.*, 2000), is withdrawn in light of Applicants' amendment to the base claims. A modified rejection is set forth below.

### **Rejection(s) Based on Applicants' Amendments**

The new rejection(s) set forth below are necessitated by Applicants' amendments to the claims, including the base claims.

#### **Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)**

- 11) Claims 48, 55 and those dependent therefrom are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 48 and 55, as amended, include the limitations: a plurality of *Neisseria* 'meningitidis' immunotypes, 'said *Neisseria meningitidis* immunotypes selected from the group consisting of L1, L3, L7, L8, L9, L10, L11 and L12'. Dependent claims 50, 51 and 52 respectively recite that 'said plurality of *Neisseria* immunotypes comprises 'three or more', 'four or more', or 'five or more' of 'said *Neisseria meningitidis* immunotypes', the lower limit of which is three, four, or five. These limitations constitute new matter, because there is no descriptive support for these limitations in the instant specification, as originally filed. The immunogenic composition recited in the claims comprises an inner core of a LPS of any generic '*Neisseria*', including non-meningococcal *Neisseria*, such as, *Neisseria gonorrhoeae*, *Neisseria lactamica*, *Neisseria sicca*, *Neisseria cinerea* etc., Furthermore, 'a *Neisseria* LPS' recited in the last line of claims 48 and 55 is

not --said *Neisseria* LPS--, and therefore it is not the same as the 'a *Neisseria* ... LPS' recited in lines 5 and 6 of the claims. As amended, the claims are now drawn to a method for eliciting in a host an antibody that recognizes, all of *Neisseria meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11 and L12, or selectively only three, four or five of *Neisseria meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11 and L12, by administering to said host an immunogenic composition comprising any neisserial LPS, with a phosphoethanolamine moiety linked to position 3 of a HepII moiety of the inner core. However, such a method has no descriptive support in the specification as originally filed. First, an immunogenic composition comprising an inner core of any non-meningococcal neisserial LPS wherein a phosphoethanolamine moiety is linked to position 3 of HepII moiety of the inner core wherein the composition elicits an antibody that recognizes all of *Neisseria meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11 and L12, or selectively only three, four or five of *Neisseria meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11 and L12, lacks descriptive support. The description in the instant specification is limited to a method of eliciting a monoclonal antibody, MAb 85, by administering an immunogenic composition comprising a formalin-killed whole cells of a *galE* mutant of *Neisseria meningitidis* of immunotype L3 wherein the monoclonal antibody is reactive with the LPS inner core of said *galE* mutant of *Neisseria meningitidis* and all of immunotypes L1, L3 and L7-12 of *Neisseria meningitidis* (see Table 2 and lines 17 and 18 of page 31). No other immunogenic composition comprising any element other than the inner core-containing formalin-killed whole cells of a *galE* mutant of any *Neisseria* other than *Neisseria meningitidis* and any immunotype other than immunotype L3 of *Neisseria meningitidis* are described in the specification, as originally filed, which composition has the ability to serve as an immunogen in a method for eliciting an antibody that recognizes all of immunotypes L1, L3 and L7-12 of *Neisseria meningitidis*, or selectively just 3, 4, or five of immunotypes L1, L3 and L7-12 of *Neisseria meningitidis*. For instance, as recited, the recognition by the recited antibody of 'three or more' of immunotypes L1, L3 and L7-12 of *Neisseria meningitidis* means that the antibody recognizes any of the three immunotypes, for example, L1, L3 and L7, but not the rest of the recited immunotypes, i.e., L8, L9, L10, L11 and L11 immunotypes of *Neisseria meningitidis*. However, a method for eliciting an antibody of such precise selective specificity by administration of the recited immunogenic composition is not described in the specification, as originally filed. Therefore, the limitations in the claims are considered to be new

matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to remove the new matter from the claim(s), or to point to specific pages and line numbers in the originally filed specification where support for such recitations can be found.

### **Rejection(s) under 35 U.S.C. § 112, Second Paragraph**

**12)** Claims 48-53 and 55-60 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 48, as amended, is vague, indefinite and appears to lack proper antecedent basis in the limitation: said inner core of ‘a *Neisseria* LPS’. The claim already includes the limitation ‘an inner core of a *Neisseria* lipopolysaccharide (LPS)’ at lines 5 and 6. Is the ‘a *Neisseria* LPS’ recited in the last line of the claim different from the one recited in lines 5 and 6 of the claim?

(b) Analogous criticism applies to claim 55.

(c) Claims 50, 51 and 52 are indefinite and have improper antecedence in the limitation ‘said plurality of *Neisseria* immunotypes’. Claims 50, 51 and 52 depend from claim 48, which recites ‘a plurality of *Neisseria meningitidis* immunotypes’, but not ‘a plurality of *Neisseria* immunotypes’. The two phrases are inconsistent in scope.

(d) Claims 50, 51 and 52 are of inconsistent and confusing scope in the limitations: ‘said plurality of *Neisseria* immunotypes comprises .... or more of said *Neisseria meningitidis* immunotypes’. The former recitation ‘*Neisseria*’ represents the neisserial genus, whereas the latter recitation ‘*Neisseria meningitidis*’ represents a specific neisserial species.

(e) Analogous criticism applies to claim 53.

(f) Claims 57, 58 and 59 are indefinite and have improper antecedence in the limitation ‘said plurality of *Neisseria* immunotypes’. Claims 57, 58 and 59 depend from claim 55, which recites ‘a plurality of *Neisseria meningitidis* immunotypes’, but not ‘a plurality of *Neisseria*

immunotypes’.

(g) Claims 57, 58 and 59 are of inconsistent and confusing in scope in the limitations: ‘said plurality of *Neisseria* immunotypes comprises .... or more of said *Neisseria meningitidis* immunotypes’. The former recitation ‘*Neisseria*’ represents the neisserial genus, whereas the latter recitation ‘*Neisseria meningitidis*’ represents a specific neisserial species.

(h) Analogous criticism applies to claim 60.

(i) Claims 55 and 60 are confusing with regard to their scope. Claim 60 includes the limitation ‘said plurality of ..... immunotypes comprises all of said ..... immunotypes’. Claim 55, from which claim 60 depends indirectly, includes the limitation: ‘each of a plurality of ..... immunotypes .... selected from the group consisting of L1, L3, L7, L8, L9, L10, L11 and L12’. It is unclear how claim 60 further limits claim 55.

(j) Claims 49-53 and 56-60, which depend directly or indirectly from claim 48 or 55, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

### **Rejection(s) under 35 U.S.C. § 102**

**13)** Claims 48-53 and 55-60 are rejected under 35 U.S.C § 102(b) as being anticipated by Plested *et al.* (*Infect. Immun.* 67: 5417-5426, October 1999, already of record).

Instant claims are not granted priority to 09/30/99 because of the lack of descriptive support for the method now claimed (see paragraph 11 above).

It is noted that the Plested reference is authored by Plested, Makepeace, Jennings, Gidney, Lacelle, Brisson, Cox, Martin, Bird, Tang, Mackinnon, Richards, and Moxon, and therefore qualifies as prior art by ‘another’ under 35 U.S.C § 102(b).

Plested *et al.* taught a method of eliciting B5 monoclonal antibody that is specific to LPS inner core comprising administering to mice an immunogenic composition comprising a formalin-killed whole cells of *galE* mutant of group B *N. meningitidis* H44/76 L3 immunotype that comprises the LPS inner core (see page 5419, right column). The inner core LPS contains an epitope recognized by the monoclonal antibody, B5, and is characterized by the presence of a phosphoethanolamine moiety linked to the 3-position at HepII of the inner core, a glucose residue at HepI, an N-acetyl glucosamine at HepII of the inner core LPS (see the upper panel of Figure 1 including the right most area indicated in bold letters). The meningococcal inner core LPS

contained in the composition consists of an inner core oligosaccharide attached to lipid A and has the general formula identical to the one recited in Figure 1a of the instant application. Plested's B5 mAb specifically recognized *N. meningitidis* immunotypes L1, L3 and L7-L12 (see Table 2). The mAb B5 induced in the prior art method by the inner core-based formalin killed meningococcal *galE* mutant whole cell vaccine is opsonic (see page 5425). Since the *galE* mutant of group B *N. meningitidis* H44/76 (L3 immunotype) used in the prior art killed whole cell preparation to raise B5 mAb is the same as the one used in the instant invention by Applicants (see first full paragraph on page 21 of the specification) and since the structure of the prior art inner core LPS is identical to the structure of the inner core LPS of the instant invention, the prior art immunogenic composition is expected to elicit antibodies of the recited immunotype specificity. Because of the same strain of *N. meningitidis* used and the identical structure of the inner core LPS, the immunogenic composition used in the prior art method is viewed as necessarily lacking the LPS outer core.

Claims 48-53 and 55-60 are anticipated by Plested *et al.*

### Remarks

**14)** Claims 48-53 and 55-60 stand rejected.

**15)** Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**16)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The central Fax



number for submission of amendments, responses and papers is (571) 273-8300.

**17)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**18)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

October, 2005

  
S. DEVI, PH.D.  
PRIMARY EXAMINER